

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Heinrich et al.

Patent No. 7,595,154

Issued: September 29, 2009

Application No. 10/517,905

Filed: December 10, 2004

Confirmation No. 4619

For: METHOD OF DETECTING A
NEOPLASIA ASSOCIATED WITH AN
ACTIVATING PLATELET DERIVED
GROWTH FACTOR RECEPTOR ALPHA
(PDGFRA) MUTATION

FILED VIA EFS

Examiner: Zachary C. Howard

Art Unit: 1646

Attorney Reference No. 899-65892-02

FILED VIA EFS
COMMISSIONER FOR PATENTS

STATEMENT UNDER 37 C.F.R. § 1.702(b)(2)

1. This statement is respectfully submitted in support of the "Petition for Patent Term Adjustment Including Request for Reconsideration Under 37 C.F.R. § 1.705(d)" for the above-referenced patent. In view of the following, it is respectfully requested that Applicants be granted a patent term adjustment of 1127 days.
2. The patent term adjustment on the issued patent is 535 days. Submitted herewith as Exhibit A is a copy of the Patent Term Adjustment History available on PAIR. This determination of 535 days is in error in that pursuant to 35 U.S.C. § 154(b) the Office failed to take certain action within the time frame specified in 37 C.F.R. § 1.702(a) and failed to issue a patent within three years of the actual filing date of the above-referenced application in accordance with 37 C.F.R. § 1.702(b).

Pursuant to 37 C.F.R. § 1.703(a), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. § 132 not later than 14 months after the actual filing date (*i.e.*, by February 10, 2006) (hereinafter "14 Month

Delay”). As the Office failed to mail an action under 35 U.S.C. § 132 until September 26, 2007, Applicants are entitled to a period of patent term adjustment beginning on the day after the date that is 14 months after the date on which the above-referenced application was filed under 35 U.S.C. § 111(a), *i.e.*, February 11, 2006, and ending on the date of the mailing of an action under 35 U.S.C. § 132, *i.e.*, September 26, 2007. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 593 days, which is in agreement with the period calculated by the Office as illustrated by Exhibit A.

In addition to the patent term adjustment due to the 14 Month Delay, pursuant to 37 C.F.R. § 1.703(b), Applicants are entitled to a period of a patent term adjustment due to examination delay from the number of days in the period beginning on the day after the date that is three years after the date on which the above-referenced application was filed under 35 U.S.C. § 111(a), *i.e.*, December 11, 2007, and ending on the date a patent is issued, *i.e.*, September 29, 2009 (hereinafter “Three Years Delay”). Accordingly, the period of patent term adjustment due to the Three Years Delays is 658 days. This delay is omitted by the Office on the PTAS Sheet (except to the extent that a portion of it may be reflected in the September 9, 2009 entry of 51 days referred to as “PTA 36 Months”).

As set forth in 37 C.F.R. § 1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays based on the grounds set forth in 37 C.F.R. § 1.702 reduced by the period of time equal to the period of time during which Applicants failed to engage in reasonable efforts to conclude prosecution pursuant to 37 C.F.R. § 1.704 (hereinafter “Applicant Delay”). Applicants delay consisted of 124 days as calculated by the USPTO (see Exhibit A).

Thus, with respect to the above-referenced application, the total period of examination delays is the sum of the period of 14 Month Delay (593 days) and the minimum period of Three Years Delay (658 days), or 1251 days, to the extent these periods of delay are not overlapping. As the period of 14 Month Delay ended on September 26, 2007, prior to the first day of the period of Three Years Delay, *i.e.*, December 11, 2007, Applicants submit that these periods are not overlapping.

To calculate the period of patent term adjustment, the total period of examination delay (1251 days) is reduced by the period of Applicant Delay, which the USPTO has calculated as a period of 124 days (see Exhibit A). Accordingly, Applicants submit that the correct patent term adjustment for the above-referenced application is 1127 days.

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 C.F.R. § 1.702 and § 1.703

Pursuant to 37 C.F.R. § 1.703(f), the period of adjustment of the term of the patent under § 1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704 (the period of Applicant Delay). In the above-referenced application, Applicants are entitled to a period of examination delay equal to the sum of the periods of delay under § 1.703(a) and (b) for the reasons set forth below.

- (i) “14 Month Delay” Pursuant to § 1.703(a)(1)

In accordance with 37 C.F.R. § 1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. § 132 not later than 14 months after the actual filing date (*i.e.*, by February 10, 2006). As shown in Exhibit A, the Office failed to mail an action under 35 U.S.C. § 132 until September 26, 2007 (when a Restriction Requirement was mailed). As such, Applicants are entitled to a period of patent term adjustment beginning February 11, 2006, and ending on September 26, 2007, the date of mailing of the Restriction Requirement by the Office. Accordingly, the period of patent term adjustment due to the 14 Month Delay by the Office is 593 days.

- (ii) “Three Years Delay” Pursuant to 37 C.F.R. § 1.703(b)

In accordance with 37 C.F.R. § 1.703(b), Applicants are entitled to a period of a patent term adjustment due to the failure by the Office to issue a patent within 3 years after the date on which the application was filed under 35 U.S.C. § 111(a) (*i.e.*, by December 10, 2007). The subject patent issued on September 29, 2009, which is 4 years and 293 days after the date on which the above-referenced application was filed under 35 U.S.C. § 111(a). As none of the exclusionary periods set forth in 37 C.F.R. § 1.702(b) apply to the instant application, and in accordance with 37 C.F.R. § 1.703, Applicants are entitled to a period of patent term adjustment beginning December 11, 2007 and ending September 29, 2009. Accordingly the period of patent term adjustment due to the Three Years Delay by the Office is 658 days.

(iii) Total Examination Delay Pursuant to 37 C.F.R. § 1.703(f)

As set forth in 37 C.F.R. § 1.703(f), the period of examination delay based on the grounds set forth in 37 C.F.R. § 1.702 is the sum of the period of 14 Month Delay (593 days) and the period of Three Years Delay (658 days), or 1251 days, to the extent these periods of delay are not overlapping. As the period of 14 Month Delay ended on September 26, 2007, prior to the first day of the period of Three Years Delay, *i.e.*, December 11, 2007, Applicants submit that these periods are not overlapping.

B. “Applicant Delay” Pursuant to 37 C.F.R. § 1.704

“Applicant delay” pursuant to 37 C.F.R. § 1.704 is that period of time during which Applicants failed to engage in reasonable efforts to conclude prosecution. As indicated on the PTAS Sheet (Exhibit A), Applicant Delay is 124 days.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 C.F.R. § 1.703(f)

As set forth in 37 C.F.R. § 1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of examination delays reduced by the period of Applicant Delay. Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is 1127 days, which is the difference between the total period of examination delay (1251 days) and the period of Applicant Delay (124 days).

4. In accordance with 37 C.F.R. § 1.705(b)(2)(iii), Applicants submit that any pending patent corresponding to this application is not subject to any terminal disclaimer.

In view of the foregoing, it is respectfully requested that this Application for Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of **1127 days**.

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Respectfully submitted,

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cc: Docketing